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(54) Percutaneous devices with flanges of variable stiffness.

(57) A percutaneous implant device (20) has a main body portion (30) and a flange (56) extending outwardly to a free edge (60) thereof from the main body portion. The flange (56) can have a thickness that decreases toward the free edge and the stiffness of the flange (56) decreases away from portions of the flange nearest the main body portion (30) to portions of the flange nearest the free edge (60). This stiffness characteristic can be accomplished by a flange density that decreases outwardly or by the flange having a porosity which increases toward the free edge. The thickness and density of the flange can decrease, while the porosity increases, toward the free edge. The thickness and thread count of a textile flange can decrease toward the free edge, or the thickness and packing density of a fibrous flange can decrease toward the free edge.

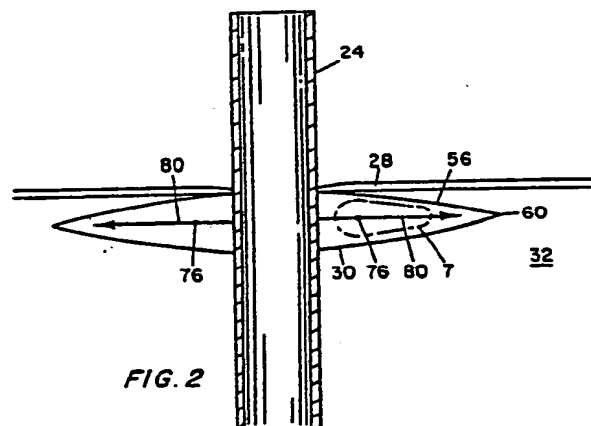


FIG. 2

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## PERCUTANEOUS DEVICES WITH FLANGES OF VARIABLE STIFFNESS

The present invention relates to implant devices and more particularly to percutaneous implant devices.

Early percutaneous devices consisted of a pipe inserted through a surgically created opening in the skin. A sufficiently bio-compatible pipe material permitted such devices to remain in situ for a few weeks to a few months, as long as the devices were not mechanically loaded. However, the weight of conduits and wires passing through these pipes mechanically loaded the pipes. Mechanical loading also resulted from the movement of the patient and handling of the conduit and wires. Such mechanical loading caused stresses and strains along the interface between the percutaneous device and the body tissue. These stresses and strains irritated the tissue and caused local inflammation and tissue destruction. In time, severe epithelial down growth occurred, and the percutaneous device failed.

Early attempts to overcome this difficulty involved the use of particular coatings along the surface of the pipe. These attempts prolonged the useful life of the percutaneous device, but not to the degree necessary for patients needing dialysis or intravenous feeding for many years.

A later attempt to overcome this difficulty focused on the design of different flanges surrounding the pipe. The basic idea of these later attempts was to distribute the forces over a larger area of contact between the skin and the subcutaneous tissue on the one hand and the implant device on the other. Several such flange designs are mentioned and discussed in Grosse-Siestrup et al, "Design Criteria for Percutaneous Devices", Journal of Biomedical Materials Research, Volume 18, pp. 357-82 (1984). The basic thickness of the flanges shown in Figs. 18-22, 24 and 25 is uniform, and the flanges are formed of a homogeneous material such as velour loops, woven or knitted structures, etc. (Fig. 22).

Another type of flange mentioned in Grosse-Siestrup et al is shown in Fig. 26 and involves a polymer textile fabric, which is uniform in thickness and density. This textile fabric flange is not as stiff as the flanges discussed above and has a stiffness closer to that of the surrounding skin and subcutaneous tissue. However, the stiffness of these textile fabric flanges increases after tissue ingrowth and produces a stiffness discontinuity along the outside rim of these textile fabric flanges. Irritations of the tissue at the flange rim occurs and finally leads to failure of these subcutaneous implants.

US-A-4.634.422 to Kantrowitz et al discloses a percutaneous access device (Figs. 6 and 7) with a flange having a peripheral section of reduced uni-

form thickness, and flanges having a thickness which gradually decreases as one moves radially outwardly from the conduit to the free edge are also known.

The present invention aims to eliminate irritation at the interface between the percutaneous device and the surrounding skin and tissue, and to increase the useful life of the device to a period of time of the order of several years.

The present invention seeks to provide a percutaneous device with a flange having decreasing stiffness from the centre to the free edge of the flange.

Still further, the present invention aims to provide a percutaneous device with a flange having a density that gradually decreases as one proceeds radially outwardly from the vicinity of the lead-through to the free edge of the flange. Again, the invention aims to provide a percutaneous device with a flange having a porosity that gradually increases as one proceeds radially outwardly from the vicinity of the lead-through to the free edge of the flange.

To achieve the objects and in accordance with the purpose of the invention, as embodied and broadly described herein, the percutaneous device of the present invention comprises a main body portion that surrounds a conduit. A flange surrounds the main body portion and extends therefrom to a free edge. The thickness of the flange may be uniform or it may decrease linearly toward the free edge and away from the main body portion. In accordance with the invention, the stiffness of the flange is varied as a function of position on the flange. The stiffness is varied so as to decrease away from the main body portion toward a free edge of the flange. Preferably, the stiffness decreases linearly. The decreasing stiffness preferably is accomplished by gradually decreasing the density of the flange, or by providing a plurality of pores in the flange such that the volume of space occupied by the pores increases away from the main body portion toward the free edge. In a textile flange, the number of threads per unit area or per square inch can be decreased away from the main body portion and toward the free edge. In a flange formed of packed felt-like fibers, the packing density of the fibers can decrease in the direction away from the main body portion towards the free edge. Preferably, the stiffness changes linearly over the flange in the direction away from the main body portion and towards the free edge of the flange. In addition, the variable stiffness can be achieved by providing an increasing volume of pores in a flange formed of material of variable

density.

The invention will now be described, non-limitatively, by way of example with reference to the accompanying drawings, in which:

Fig. 1 shows a perspective view of a device according to the present invention;

Fig. 2 illustrates a cross-section of the device of Fig. 1 implanted in a living host;

Fig. 2a illustrates an expanded view of a schematic cross-section taken from an embodiment such as shown in Fig. 2 for example;

Fig. 3 illustrates a perspective cut away view of a second embodiment of the present invention;

Fig. 4 illustrates a cross-sectional view of the device in Fig. 3 implanted in a living host;

Fig. 5 illustrates a partial cross-sectional view of a third embodiment of the present invention;

Fig. 6 illustrates a cross-sectional view of a fourth embodiment of the present invention; and

Fig. 7 illustrates an expanded view of a schematic cross-section taken from an embodiment such as shown in Fig. 6 for example.

A preferred embodiment of the pharmaceutically protected percutaneous implant device of the present invention is shown in Fig. 1 for example and is represented generally by the numeral 20.

The percutaneous device of the present invention includes a conduit for leading through the skin of a living human being or animal. As embodied herein and shown for example in Figs. 2 and 4, a conduit 24 in use extends through an opening through skin 28 in a living human being or animal. Conduit 24 comprises a tube or pipe that also passes through the body's subcutaneous tissue 32. Conduit 24 preferably is formed of a bio-compatible material such as silicon, titanium, and polycarbonate. Preferably, only the tissue-interfacing surface of the conduit need be formed of a bio-compatible material. Accordingly, various composite structures are suitable as conduits for purposes of the present invention.

The device of the present invention further includes a main body portion. As embodied herein and shown in Figs. 1-6 for example, the main body portion 30 is integral with or in contact with the exterior wall of conduit 24.

In further accordance with the present invention, a flange extends outwardly from the main body portion and has a free edge. As embodied herein and shown in Figs. 1-6 for example, a flange 56 extends radially outwardly from main body portion 30 and terminates in a free edge 60. Flange 56 preferably surrounds main body portion 30 and extends radially outwardly therefrom. Main body portion 30 can be integral with flange 56, as desired.

In further accordance with the present inven-

tion, means are provided for varying the stiffness of different portions of the flange so that the stiffness decreases as an imaginary point proceeds from portions of the flange nearest the main body portion to portions of the flange nearest the free edge. As embodied herein and shown in Figs. 2-6, the stiffness of flange 56 preferably decreases gradually as an imaginary point 76 moves in the direction of arrow 80 from the portion of flange 56 contacting conduit 24 to free edge 60. As embodied herein and shown in Fig. 2 for example, the stiffness varying means in a flange having a linearly decreasing thickness preferably includes a decreasing density of the flange as the imaginary point moves from the main body portion to the free edge. As shown in Fig. 2a for example, the density decreases as one proceeds from left to right, which corresponds to movement from the vicinity of conduit 24 toward free edge 60. This decreasing density results in a decreasing stiffness of the flange. In an alternative embodiment shown in Figs. 6 and 7 for example, flange 56 can have a uniform thickness and the stiffness varying means preferably includes a plurality of pores wherein the volumetric density of the pores increases as an imaginary point moves from the portion of flange 56 contacting conduit 24 to free edge 60. As shown in Figs. 3 and 4 for flanges formed of fabric for example, the stiffness varying means preferably includes decreasing thread counts as an imaginary point 76 proceeds from the main body portion toward free edge 60 of the flange. In other words, the number of individual thread strands per square inch of flange decreases as an imaginary point moves from conduit 24 to free edge 60. As shown in flanges formed of felt-like fibrous materials in Fig. 5 for example, the stiffness varying means preferably includes a decreasing packing density of fibers. The stiffness varying means of the flange also can include a combination of some of the foregoing structural techniques, such as for example an increasing porosity within a tapered flange of decreasing density.

As depicted schematically by decreasing density of shading in Fig. 2a for example, the stiffness preferably can be decreased by linearly decreasing the density of a flange as one proceeds from the main body portion to the free edge. As represented schematically in Fig. 7 for example, the stiffness of a flange of uniform thickness can be decreased by linearly increasing the number or size of pores as one proceeds from the main body portion to the free edge.

As an imaginary point moves through the flange, it encounters different densities of the material forming the flange. Thus, the local density changes as a function of the position of the point within the flange. The combination of the individual

local density characteristics constitutes a density profile for the flange. Similarly, if one provides the material forming the flange with a plurality of pores, one can use the porosity characterizing different local positions within the flange to obtain a porosity profile. In the present invention, the porosity profile is such that the volume of space occupied by the pores increases, preferably linearly, as an imaginary point moves from nearest the main body portion to the free edge. This can be accomplished by an increasing number of pores or an increase in the size of individual pores, or both.

Each of the main body portion 30 and the flange 56 preferably is formed of one or more of the following materials: silicone rubber, polytetrafluoroethylene, acrylic copolymers cast on polymeric substrates such as VERSAPOR manufactured by Gelman Sciences of Ann Arbor, Michigan, polysulfone, polyurethanes, polyethylene, and nylon. Such materials can be formed with varying densities and porosities by known techniques, and these densities and porosities can be controlled to optimize them for a preselected degree of stiffness and a desired flexibility characteristic.

It will be apparent to those skilled in the art that various modifications and variations can be made in the present invention without departing from the scope of the claimed invention. Thus, it is intended that the present invention cover modifications and variations that come within the scope of the appended claims and their equivalents.

## Claims

1. A percutaneous device comprising:
  - (a) a main body portion (30);
  - (b) a flange (56) extending outwardly from the main body portion and having a free edge (60); and
  - (c) means for varying the stiffness of different portions of the flange (60), the said stiffness decreasing as an imaginary point proceeds from portions of the flange (56) nearest the main body portion (30) to portions of said flange nearest the free edge (60), the stiffness varying means including a plurality of pores in the flange (56), wherein the volume of space occupied by the pores increases as the imaginary point moves from adjacent the main body portion to the free edge.
2. A device according to claim 1, wherein the volume of space occupied by the pores increases linearly towards the free edge (60).
3. A percutaneous device comprising:
  - (a) a main body portion (30);
  - (b) a flange (56) surrounding the main body portion and having a free edge (60), the flange extending radially from the main body portion (30)

to the free edge and having a thickness which decreases as the imaginary point moves from the main body portion (30) to the free edge (60); and

(c) means for varying the stiffness of the flange (56) as a function of the radial position of an imaginary point in the flange, the stiffness decreasing as the imaginary point moves from adjacent the main body portion toward the free edge (60), the stiffness varying means including a density profile in the flange wherein the density decreases as the imaginary point moves from adjacent the main body portion toward the free edge.

4. A device according to claim 3, wherein the profile has the density decreasing linearly as the imaginary point moves from adjacent the main body portion toward the free edge.

5. A device according to any of claims 1 to 4, wherein the flange thickness decreases linearly as the imaginary point moves from adjacent the main body portion towards the free edge.

6. A percutaneous device comprising:

(a) a main body portion (30);

(b) a flange (56) extending outwardly from the main body portion (30) and having a free edge (60), the flange comprising a plurality of threads; and

(c) means for varying the stiffness of different portions of the flange (56), the stiffness decreasing as an imaginary point proceeds from portions of said flange adjacent the main body portion (30) to portions of said flange (56) adjacent free edge (60), wherein the stiffness varying means includes a thread count which decreases outwardly as the imaginary point moves from adjacent the main body portion towards the free edge.

7. A device according to claim 6, wherein the thread count decreases linearly as the imaginary point moves from adjacent main body portion (30) toward the free edge (60).

8. A percutaneous device comprising:

(a) a main body portion (30);

(b) a flange (56) surrounding the main body portion and having a free edge (60) which extends radially from the main body portion to the free edge, the flange comprising a plurality of fibers; and

(c) means for varying the stiffness of the flange (56) as a function of the radial position of an imaginary point in said flange, the stiffness decreasing as said imaginary point moves from adjacent the main body portion (30) towards the free edge (60), wherein the stiffness varying means includes a decreasing packing density of fibers forming the flange as said imaginary point moves from adjacent the main body portion towards the free edge.

9. A device according to claim 8, wherein the fiber packing density decreases linearly as the

imaginary point moves outwardly from adjacent the  
main body portion towards the free edge.

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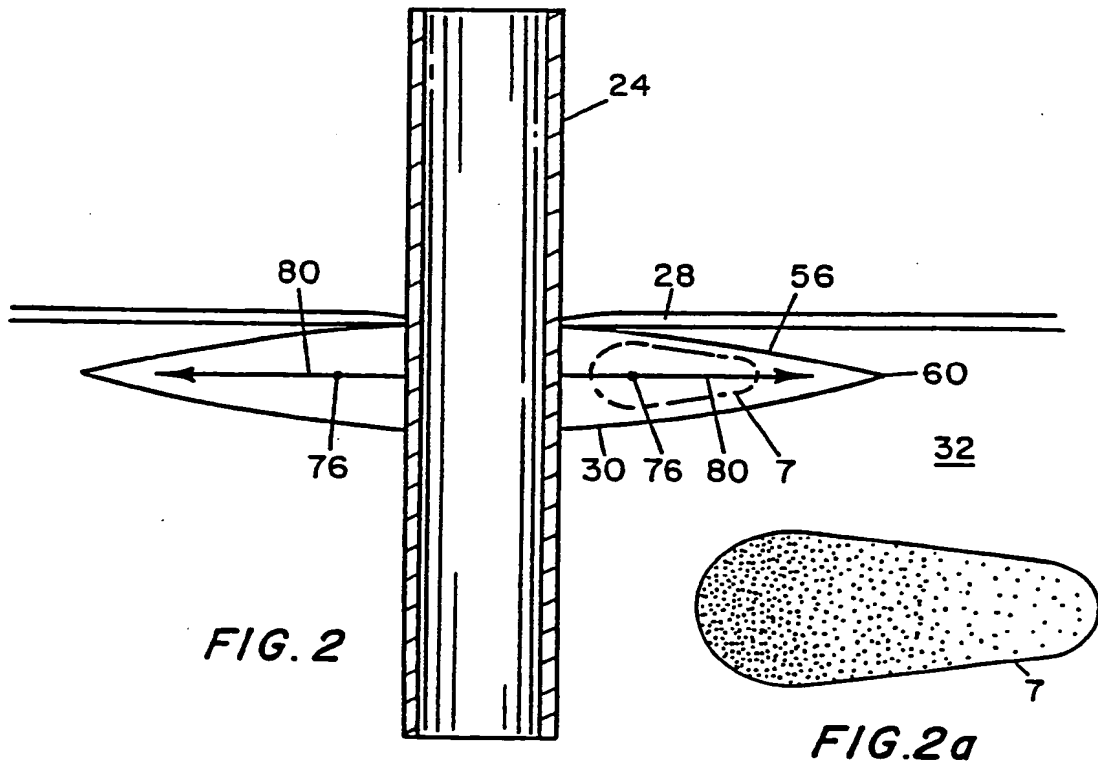
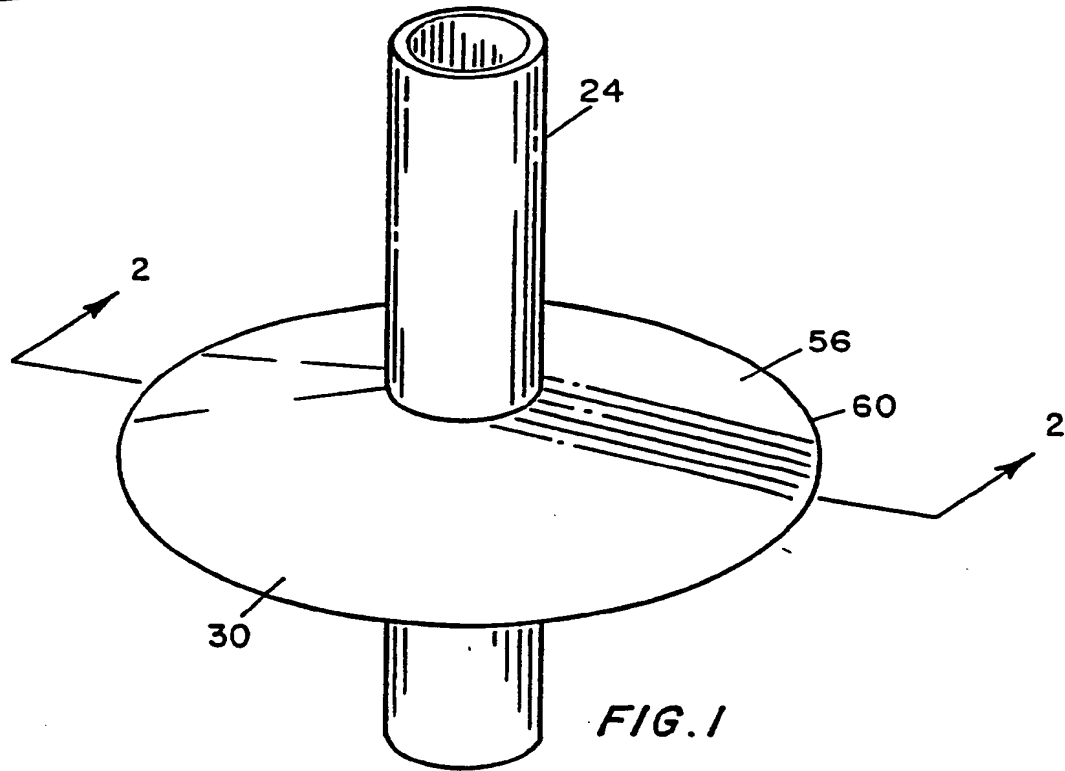
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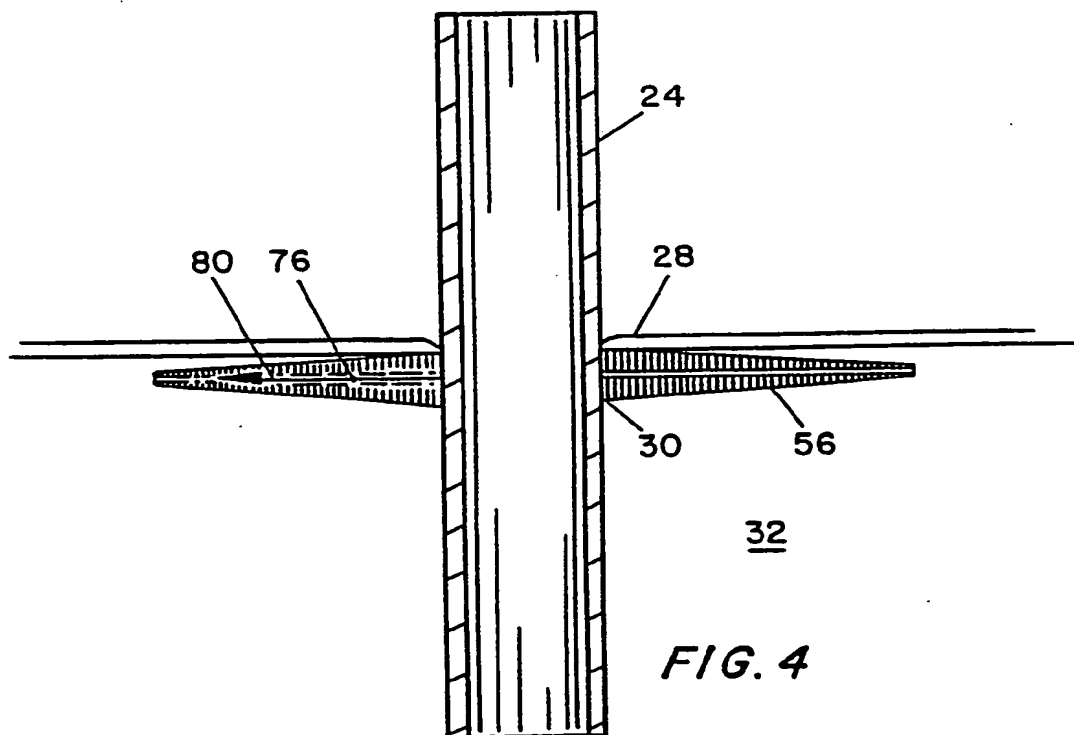
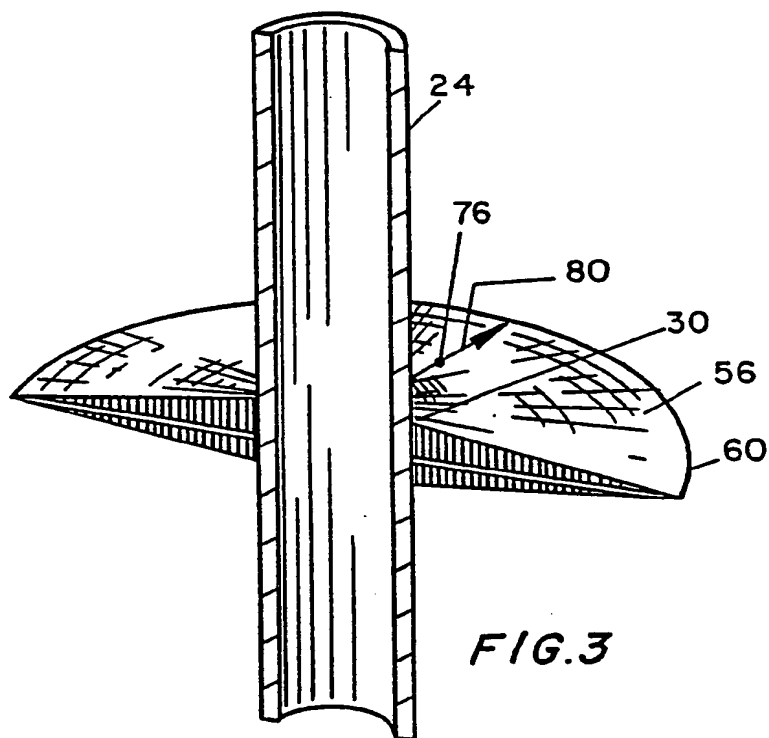
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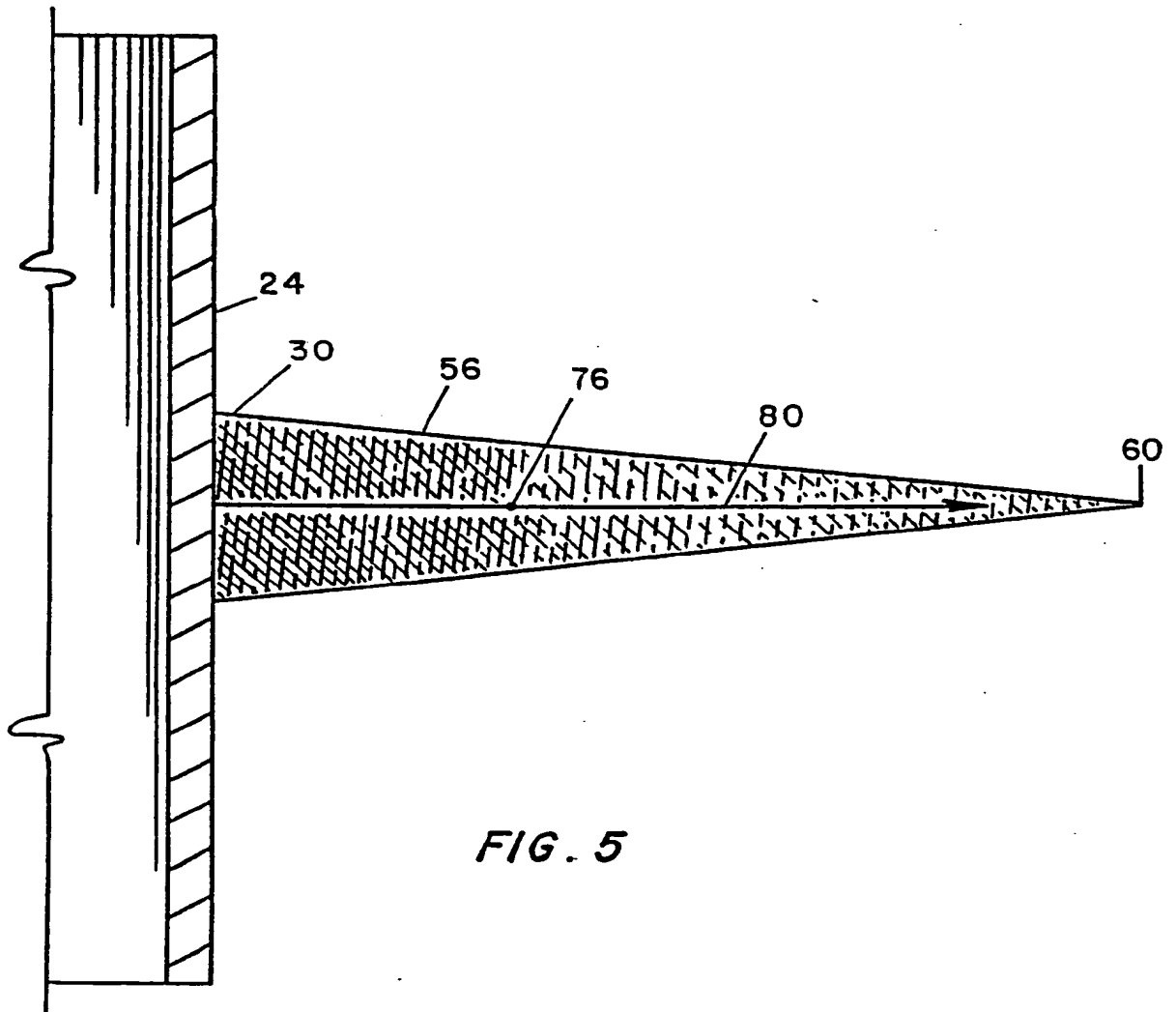
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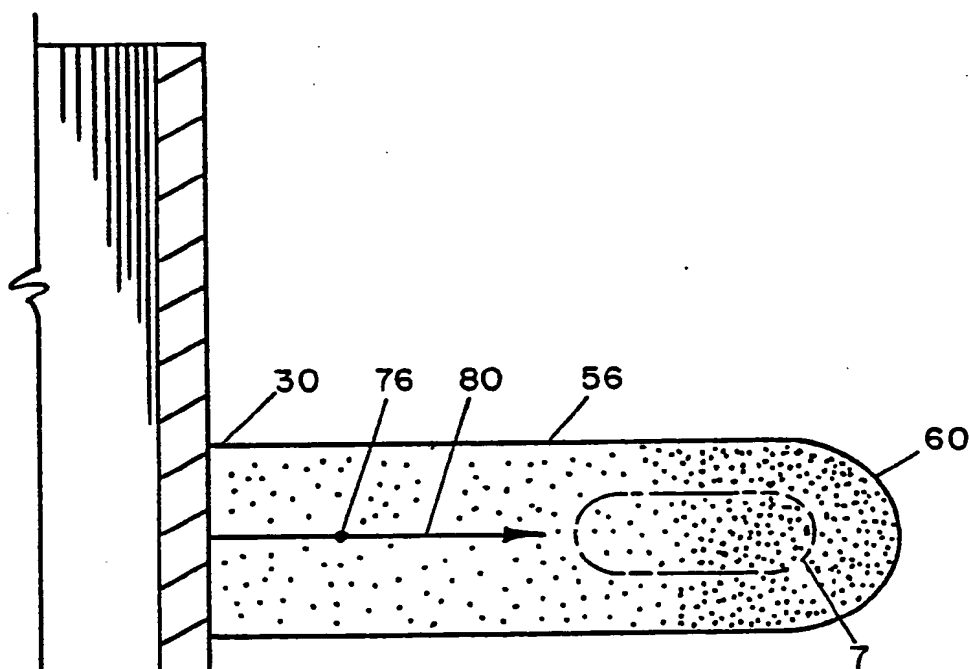


FIG. 6

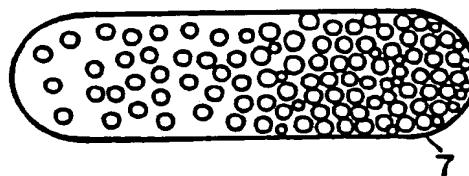


FIG. 7

⑫ **EUROPEAN PATENT APPLICATION**

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⑴ Applicant: CLEMSON UNIVERSITY

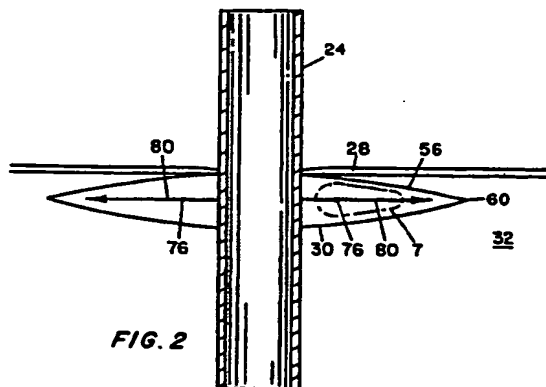
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# EUROPEAN SEARCH REPORT

Application Number

EP 90 30 1315

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. CL5)
X	EP-A-0 164 896 (THERMEDICS INC.) * Abstract; claim 1; figure 2 *	1	A 61 M 1/00
Y		3	
A		6,8	
Y	EP-A-0 174 802 (W.L. GORRE & ASSOCIATES, INC.) * Abstract; claim 1; figures 1,2 *	3	
A	EP-A-0 207 817 (BIOMASYS) * Abstract; page 7, lines 30-36; figure 1 *	1,3,6,8	
A	FR-A-2 460 129 (UNION CARBIDE CORP.) * Page 4, lines 23-31 *	1,2	
			TECHNICAL FIELDS SEARCHED (Int. CL5)
			A 61 M
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 01-10-1990	Examiner ZEINSTRA H.S.J.H.
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

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